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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/704,327

11/01/2000

James M. Lipton

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EXAMINER
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WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/704,327

Applicant(s)  
Lipton

Examiner  
Randall Winston

Art Unit  
1654

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 and 5 6) ☐ Other:

Art Unit: 1654

## **DETAILED ACTION**

### ***Election/Restriction***

Acknowledgment is made of receipt and entry of the election filed on May 21, 2002.

Claims 21-40 are under examination.

### ***Election/Restriction***

Applicants' election with traverse of Group II, Claims 21-40 in Paper No.9 is acknowledged. The traversal is on the grounds that the applicant argues that unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Applicants' argument is not found persuasive because, as the Examiner explained in the Restriction Requirement (Paper No. 6), claims 1, 21, 41 and 61 are generic to a plurality of disclosed patentably distinct species comprising (SEQ.ID. NO.1) or (SEQ.ID.NO.2) or (SEQ.ID.NO.3) or (SEQ.ID.NO.4). The amino acid sequences are different variables as disclosed by the instant specification of one another that inherently would cause a different effect.

The restriction requirement is still deemed proper and is therefore made final.

### ***Claim Rejections - 35 USC § 112***

Art Unit: 1654

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is made vague and indefinite by the term “including.” Applicant may overcome the rejection by clearly defining “including”. (Is the polypeptide the amino acid sequence? or polypeptide and the amino acid sequence separate?)

Claim 36 recites the terms “biologically functional equivalent of anything of the foregoing.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning “biologically functional equivalent of anything of the foregoing.” There is no definition of “biologically functional equivalent of the foregoing” in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. (Please note Does the amino acid sequence act as a sunscreen or as a sequence? thus, since applicant states in its claim a biologically functional equivalent of the foregoing is the biologically functional equivalent of applicant’s claimed sequence (i.e. SEQ.ID.NO.1) the same as any other sunscreen ingredient such as zinc oxide?)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Art Unit: 1654

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-40 are rejected under 103(a) as being unpatentable over Rathjen et al.(WO 93/012211)

Applicant claims sunburn treatment kit comprising of a liquid impermeable packaging, an absorbent material, a carrier, and at least one polypeptide of the KPV (SEQ.ID.NO.1) for inflammation.

Rathjen et al. teach peptides that include sequence KPV(SEQ.ID.NO.1) and that act as an active ingredient and methods of anti-inflammatory treatment (e.g. treating dermatitis and/or psoriasis) that includes a carrier (see, e.g. abstract, page 1 line 1-8 and page 7 lines 32.) Rathjen et al. do not teach the peptide contained within a kit that includes liquid impermeable packaging and an absorbent material. However, one of ordinary skill in the art would have been motivated to modify Rathjen et al. 's teaching to include the adjustment of these other conventional working conditions (e.g., liquid impermeable packaging and an absorbent material), because these other conventional working conditions are deemed merely a matter of judicial selection and

Art Unit: 1654

routine optimization which is well within the purview of the skilled artisan to create a kit to treat inflammation. Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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A handwritten signature in black ink, appearing to be 'CR Tate', written in a cursive style.

CHRISTOPHER R. TATE  
PRIMARY EXAMINER